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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

May 13, 2013

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee Markup of H.R. 271, Resolving Environmental and Grid Reliability Conflicts Act of 2013; H.R. 1407, the Animal Drug User Fee Amendments Act of 2013, and H.R. 1919, Safeguarding America's Pharmaceuticals Act of 2013

On Tuesday, May 14, 2013, at 4:00 p.m. in room 2123 of the Rayburn House Office Building, the Energy and Commerce Committee will meet in an open markup session for opening statements on three bills: 1) H.R. 271, Resolving Environmental and Grid Reliability Conflicts Act of 2013; 2) H.R. 1407, the Animal Drug User Fee Amendments Act of 2013, as amended by the Subcommittee on Health; and 3) H.R. 1919, Safeguarding America's Pharmaceuticals Act of 2013. The Committee will reconvene on Wednesday, May 15, 2013, at 10:00 a.m. in room 2123 of the Rayburn House Office Building in open markup session on these bills.

I. H.R. 271, RESOLVING ENVIRONMENTAL AND GRID RELIABILITY CONFLICTS ACT OF 2013

A. Background

Section 202(c) of the Federal Power Act provides the Secretary of the Department of Energy (DOE) with the authority to require the generation, transmission, or delivery of electricity, or the temporary connection of facilities when there is a war or other emergency situation that creates a sudden increase in the demand for electricity, a shortage of electricity or facilities for the generation or transmission of electricity, or a shortage of fuel or water for generating facilities. The resulting costs are recovered through existing rate schedules, negotiated rates, or, in the event the parties are unable to agree on a rate to be charged, through a rate established by the Federal Energy Regulatory Commission (FERC).

This emergency order authority has only been used on six occasions, only two of which involved ordering generation facilities to run.[1]

During the California energy crisis, the Secretary issued an emergency order directed to the California Independent System Operator (CAISO) and a group of electricity generators that supplied the CAISO. The order required the generators to provide electricity to the CAISO on any day that the CAISO found itself unable to acquire an adequate supply of electricity to meet demand. The order and a subsequent order were in effect from December 14, 2000, until February 7, 2001.

On August 16, 2002, due to concerns regarding the availability of electricity on Long Island in New York, a 202(c) order was issued directing Cross-Sound Cable Company to operate the Cross-Sound Cable from Connecticut to Long Island. The order expired on October 1, 2002.

On August 14, 2003, in response to a major blackout in the Northeast, upper Midwest, and portions of Canada, the Secretary directed the New York Independent System Operator and ISO New England to require Cross-Sound Cable Company to operate the Cross-Sound Cable and related facilities. The emergency order was terminated on May 7, 2004.

On September 28, 2005, in response to "the massive devastation caused by Hurricane Rita, which further exacerbated the dire conditions caused by Hurricane Katrina," a 202(c) emergency order was issued directing CenterPoint Energy to temporarily connect electricity lines to restore power to Entergy Gulf States, Inc., as well as electric cooperatives and municipal customers within the state of Texas. On September 30, 2005, also in response to Hurricane Rita, a 202(c) emergency order was issued directing TXU Electricity Delivery to temporarily connect and energize a line for the purpose of delivering electricity to the Deep East Electric Cooperative. Both of these emergency orders expired on November 1, 2005.

Similarly, on September 14, 2008, in response to Hurricane Ike, the Secretary issued a 202(c) emergency order directing CenterPoint Energy to temporarily connect electricity lines to restore power to Entergy Gulf States, Inc., as well as electric cooperatives and municipal customers within the state of Texas. That order expired on November 1, 2008.

The only instance of a 202(c) order requiring actions that potentially would result in noncompliance with environmental laws and regulations involved Mirant Corporation's coal-fired Potomac River generating station, which provided electricity to Washington, D.C. On August 24, 2005, Mirant shut down the facility after a Mirant study showed that emissions from the facility resulted in modeled violations of the National Ambient Air Quality Standards (NAAQS) for sulfur dioxide, nitrogen oxide, and particulate matter. That day, the District of Columbia Public Service Commission petitioned the Department of Energy for an emergency order requiring Mirant to continue operating the Potomac River facility. The plant was one of three sources of electricity serving central D.C. and a large wastewater treatment plant located in

[1] All 202(c) emergency orders issued by the Secretary of Energy are available at http://energy.gov/oe/does-use-federal-power-act-emergency-authority. More than six orders were issued because some situations involved more than one order.

the city. The other two sources were 230 kilovolt transmission lines that delivered electricity from other generating facilities outside of D.C.

Almost four months later, on December 20, 2005, a 202(c) emergency order was issued requiring Mirant to operate the Potomac River generating station. The Secretary made a determination that, without the operation of the facility, there was a "reasonable possibility an outage would occur that would cause a blackout" in the central D.C. area. The Secretary concluded that "the Plant must be available to run when one of the 230 kV lines is out of service, because if the remaining line failed there would be no other source of electricity to service the Central D.C. area load." A subsequent order with substantially the same terms remained in effect until July 1, 2007, when two new transmission lines had been completed.

On June 1, 2006, the Environmental Protection Agency (EPA) and Mirant entered into an administrative compliance order, which required specific emission reduction measures during operation of the Potomac River plant. However, the facility exceeded a limit on sulfur dioxide emissions on February 23, 2007. The Virginia Department of Environmental Quality issued a notice of violation and subsequently fined Mirant for the exceedances.

B. Summary of Bill

Rep. Olson introduced H.R. 271 on January 15, 2013, with Reps. Doyle, Terry, Green, and Kinzinger as original cosponsors. The bill is identical to H.R. 4273, which was favorably reported by the Committee with bipartisan support during the last Congress and passed the House by voice vote on August 1, 2012.

Section 2(a) of the bill amends section 202(c) of the Federal Power Act to direct DOE, in issuing an order pursuant to section 202(c) that may result in a conflict with a requirement of any federal, state, or local environmental law or regulation, to ensure that the order limits the generation, delivery, or transmission of electricity to only those hours necessary to meet the emergency and serve the public interest. DOE also must ensure the order, to the maximum extent practicable, is consistent with any applicable Federal, State, or local laws or regulations and minimizes any adverse environmental impacts that may result from such order.

Section 2(a) further amends section 202(c) to provide that if a party takes an action that is necessary to comply with a section 202(c) order and such action results in noncompliance with any Federal, State, or local environmental law or regulation, then the action shall not be considered a violation of such environmental law. Nor would the action subject the party to any requirement, civil or criminal liability, or a citizen suit under the environmental law. This provision also applies to actions taken by parties that may not be legally required to comply with a section 202(c) order but voluntarily choose to comply..

Section 2(a) further amends section 202(c) to require that an order issued pursuant to section 202(c) that may result in a conflict with an environmental law or regulation shall expire no later than 90 days after issuance. DOE may renew or reissue an order for subsequent periods, not to exceed 90 days, as it determines necessary to meet the emergency and serve the public interest. In renewing or reissuing the order, DOE must consult with the primary federal agency

with expertise in the environmental interest protected by a potentially conflicting environmental law. DOE must include in the renewed or reissued order conditions determined by such primary federal agency to be necessary to minimize any adverse environmental impacts that may result from such renewed or reissued order to the maximum extent practicable. The conditions formally submitted to DOE by the primary federal agency shall be made available to the public. DOE has discretion to exclude a condition from the renewed or reissued order if it determines the condition would prevent the order from adequately addressing the emergency. DOE must provide an explanation of any determination to exclude a condition and make it publicly available.

Section 202(d) of the Federal Power Act provides that, during an emergency, an individual or corporation engaged in the transmission or sale of electricity that is not otherwise subject to FERC jurisdiction, such as a rural electric cooperative, may make temporary connections with a regulated utility without becoming subject to FERC jurisdiction. The bill would amend section 202(d) to apply this provision to municipalities.

II. H.R. 1407, ANIMAL DRUG USER FEE AMENDMENTS ACT OF 2013, AS AMENDED BY THE SUBCOMITTEE ON HEALTH

Please see the Republican markup memorandum for a summary of the bill. In addition to Rep. Shimkus, H.R. 1407 was introduced by Reps. Gardner, Upton, Pitts, Waxman, Pallone, Burgess, Guthrie, and Kinzinger. The bill represents the FDA-industry negotiated user fee agreements and the Democratic staff does not anticipate any amendments.

III. H.R. 1919, SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT OF 2013

On April 25, 2013, the Subcommittee on Health examined a discussion draft by Reps. Latta and Matheson at a legislative hearing titled "Securing Our Nation's Prescription Drug Supply Chain.". Information from that hearing, including testimony and the Latta-Matheson discussion draft is available here: http://democrats.energycommerce.house.gov/index.php?q=hearing/hearing-on-securing-our-nation-s-prescription-drug-supply-chain-subcommittee-on-health-april.

Please also see the hearing memo from the Democratic staff which is attached. At the hearing, the Subcommittee discussed a report issued by Representative Cummings and Senators Rockefeller and Harkin detailing companies that buy and sell drugs that are in shortage outside of the authorized distribution networks, resulting in exorbitant prices. That report may be found here: http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=afa98935-2ff5-4004-88dc-be70d1c22b5d.

On May 3, 2013, the Republican Committee staff circulated a new discussion draft, which was the subject of the Subcommittee on Health markup on May 8, 2013. The May 3, 2013, discussion draft made certain revisions to the Latta-Matheson Discussion Draft in response to concerns.

At the Subcommittee markup, many Democratic members raised significant concerns regarding the May 3, 2013, discussion draft and discussed those issues at the markup. No amendments were offered; however, after discussion among members, it was agreed that staff work to develop consensus between Subcommittee and Full Committee markups. On May 8, 2013, the Subcommittee on Health approved the May 3, 2013, discussion draft by a voice vote. On May 9, 2013, Reps. Latta and Matheson introduced H.R. 1919, which is similar to the May 3, 2013, discussion draft approved by the Subcommittee on Health, except that a formal title of the bill was added and technical changes were made.

The following information supplements the summary provided in the May 10, 2013, Republican markup memorandum and details the issues and concerns that remain in H.R. 1919. Additionally, the following indicates where there are significant differences between H.R. 1919 and the draft bipartisan Senate legislation which was distributed on April 19, 2013, by Senators Bennet, Burr, Harking and Alexander. That legislation and a section by section summary can be found here: http://www.help.senate.gov/newsroom/press/release/?id=bae48b5b-9109-4081-817e-7d208d96f177&groups=Ranking.

A. Section 2: Pharmaceutical Distribution Supply Chain

One issue that is reflected in Section 2 is the problem of how to handle "returns," which generally refers to entities in the supply chain having the ability to return unused stock to the previous seller from which they obtained the product. As discussed at the Subcommittee's legislative hearing, returns create the potential for entry of illegitimate product, a serious problem. For example, pharmacies could obtain counterfeit or substandard medicines and sell them back to the wholesaler at a profit, and then the wholesaler could redistribute that product into the supply chain.

H.R. 1919 only partially addresses this issue. The bill provides that if a wholesaler accepts product from a dispenser without transaction history, upon redistributing that product, the wholesaler must begin a new transaction history.[2] In other words, upon redistributing the product, the pedigree starts anew with the wholesaler.

The Senate draft includes these requirements but goes further. Once wholesalers begin engaging in transactions only with serialized product (beginning six years after enactment), the Senate bill would prohibit wholesalers from accepting product from dispensers unless the wholesaler could associate the returned product with the transaction history and information linked to that product.[3] This requirement ensures that the wholesaler will verify that the returned product from the dispenser was indeed the product that the wholesaler sold to that dispenser. As a result, the likelihood of counterfeit or substandard product entering the supply chain is diminished.

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[2] *See* H.R. 1919, at 34 lines 19-23.

[3] *See* S. _____, To amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain, at 37 line 15-38 line 12 (Apr. 19, 2013) (online at http://www.help.senate.gov/newsroom/press/release/?id=eefc5f60-c529-4d37-82d5-65ae3a9ee09f&groups=Ranking,Chair).

B. Section 3: Enhanced Drug Distribution Security

There is widespread agreement that, if the goal is to protect American patients from substandard and falsified medicines, the best way to protect the supply chain is to establish an interoperable unit-level system that involves all members of the supply chain. One of the key issues reflected in both the House and Senate draft legislation is how and when to establish this kind of system. In general, section 2 of H.R. 1919 sets up a so-called "phase I" in which certain aspects of this system are put in place. Section 3 represents the so-called "phase II" in which the goal is to establish this system. However, for the following reasons, there is a concern that this goal will not fully be realized based on the current language of the bill.

H.R. 1919 would require the Food and Drug Administration (FDA) to issue *proposed* regulations, no sooner than January 1, 2027, and no later than March 1, 2027.[4] These proposed regulations would establish additional requirements "to prevent a suspect product, illegitimate product, or a product that is counterfeit, stolen, diverted, or otherwise unfit for distribution from entering into or being further distributed in the supply chain."[5] Such requirements would include those "related to the use of interoperable electronic systems and technologies for enhanced tracing of prescription drug product at the package level" among other things.[6]

The bill does not set a deadline for the issuance of final regulations, but it does mandate that, if and when final regulations are issued, there is a two year delay in the effective date of those regulations.[7]

C. Section 4: National Standards for Wholesale Distributors

H.R. 1919 requires FDA to set national standards for the licensing of wholesale distributors[8] and preempts all state laws governing such licensure that are "inconsistent with, less stringent than, in addition to, or more stringent than" the standard that FDA will set.[9] In other words, the draft would make the FDA standards both a "ceiling and a floor" for state licensing laws. This can be a concern for states that have a high number of wholesalers and, consequently, strong licensing schemes. An alternative approach, set forth in the Senate bill, is to require FDA to set standards, but permit states to go beyond those standards when appropriate— the FDA standards under the Senate bill are a floor, but not a ceiling.[10]

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[4] *See* H.R. 1919, at 70, line 13.

[5] *See* H.R. 1919, at 70, lines 20-24.

[6] *See* H.R. 1919, at 71, lines 1-4.

[7] *See* H.R. 1919, at 75, lines 1-3.

[8] See H.R. 1919, at 75, line 19.

[9] See H.R. 1919, at 93, line 17.

[10] *See* S. _____, To amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain, at 105 lines 10-22 (Apr. 19, 2013) (online at

D. Section 7: Uniform National Policy

On the date of enactment, H.R. 1919 would preempt all state requirements for tracing drugs through the distribution system, as well as current federal requirements that were set forth in Section 503(e) of the Federal Food, Drug, and Cosmetic Act, as part of the Prescription Drug Marketing Act of 1987. For example, Florida requires that a pedigree identifying each previous sale of a drug back to the manufacturer be passed with most drug transactions. Under H.R. 1919, there would be no federal requirement to pass transaction information and history until January 1, 2015, for manufacturers and repackagers,[11]April 1, 2015 for wholesalers,[12]and July 1, 2015 for dispensers.[13] Thus, state and federal requirements would be preempted before any federal requirements to pass transaction information and history have kicked in. As discussed at the Subcommittee's legislative hearing, assuming the current draft were to be enacted during 2013, this would leave a significant gap in the current level of information about a drug's path through the supply chain—information that is important to law enforcement efforts to stop the entry of counterfeit and substandard drugs into the supply chain.

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http://www.help.senate.gov/newsroom/press/release/?id=eefc5f60-c529-4d37-82d5-65ae3a9ee09f&groups=Ranking,Chair).

[11] See H.R. 1919, at 24, lines 7-16; 49, line 22-50, line 6.

[12] See H.R. 1919, at 31, line 18-34, line 11.

[13] See H.R. 1919, at 41, line 18-42, line 16.